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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,666	02/11/2004	Tushar Patel	101896-0233	3475
21125	7590	01/03/2006	EXAMINER	
NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			AMARELD JR, ROBERT W	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 01/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/776,666

Applicant(s)

PATEL ET AL.

Examiner

Robert W. Amareld, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24, 26-28, 30, 31, 33-38, 45, 46, 48 and 85-93 is/are pending in the application.
- 4a) Of the above claim(s) 25, 29, 32, 39-44, 47 and 49-85 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24, 26-28, 30, 31, 33-38, 45, 46, 48 and 85-93 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10/21/04, 5/7/04, 6/30/04, 10/21/04, 9/17/04
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election **with traverse** of species D in the reply filed on 12/6/05 is acknowledged. The traversal is on the ground(s) that grouping of species are incorrect. This is found persuasive after review of the drawings.

The requirement is now deemed proper and is therefore made FINAL.

Claims 25, 29, 32, 39-44, 47, 49-85<sup>and by 1/4/2006</sup> withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group/species, there being no allowable generic or linking claim.

### ***Double Patenting***

Claims 26-30 of this application conflict with claims 19-23 of Application No. 10/409,958. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

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from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-5, 14-19, 22, 23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8, 12-14 of copending Application No. 10/409,958. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 11-13, 15-23, 26, 28, 30, 31, 36-38, 45, 46, 48, 86-93 are rejected under 35 U.S.C. 102(b) as being anticipated by Coates (US Pat# 5423826). Coates discloses an elongate support member, first and second arms (152, 151), transverse to and coupled to the support member at the distal end, both arms being either fixed or slidably movable along the threads on the support member (column 13 lines 58-67) and each arm having a guide member (157) on its proximal end, with two pathways (158) capable of receiving a tool (Figure 16) and for juxtapositioning on a spinal implant (22) such that the bores are aligned (Figure 19) and the plate fits into the groove and hooks of the guide (159/161) which match the contour of the spinal plate. The arms have a distal portion that is at an angle to the proximal portion (Figure 20). Each guide member (157) comprises a housing with opposed first and second pathways (Figure 16) where the housing contains a lumen sleeve (180) which has a rounded tip extends through the barrel into the rounded recess of the accompanying plate. Each pathway in the guide is in communication with each other through the material of the guide and has a cut out portion (159/161) formed in the housing between the first and second pathways (Figure 16) where the cut out portion extends from the housing where the pathways (158) are in

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communication through the body of the guide. In one embodiment of the guide the bores are in communication through the overlap (121, Figure 11). The c-shaped hooks (161) extend from the distal end of the guide member and are opposed tabs which are opposed to the spinal plate (22) and have the bores (158) between them where the tabs have a shape adapted to match the contour of the plate and fit into the slot of the plate on the perimeter of the plate. The support member (155) has adjustment knob (154), which allows either arm to move along the adjustment threads of the lockable support member (column 13 lines 50-67). Please note the intended use, as set forth in the claims, carries no weight in the absence of any distinguishing structure.

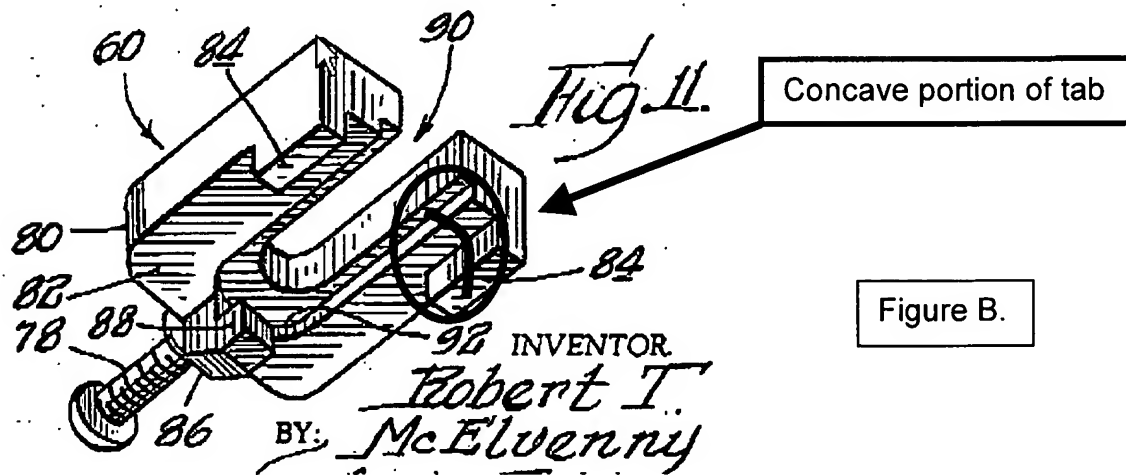
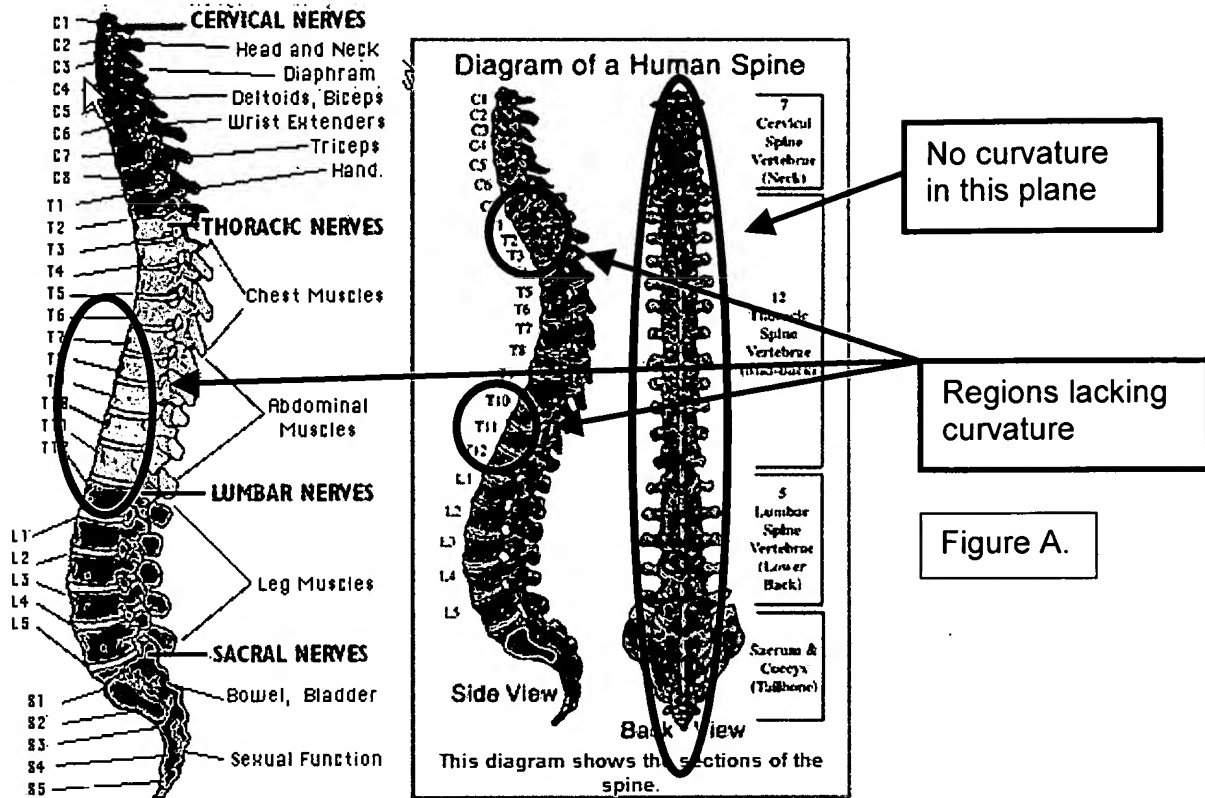
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are*

Claims 1, 3, 4, 6, 7, 8, 9, 10, 14, 19, 21, 22, 23, 24, 26, 27, 30, 31, 37<sup>^</sup> rejected under 35 U.S.C. 102(b) as being anticipated by McElvenny. McElvenny discloses a guide device with 1<sup>st</sup> and 2<sup>nd</sup> arms (76) with proximal end coupled to the support member (54) where the 1<sup>st</sup> and 2<sup>nd</sup> arm carriage (56, 58) are slidably or fixedly movable along the support member (column 3, lines 30-33), the end of each arm containing a guide member (60), which comprises a housing containing first and second pathways, the first being the notch (90) and the second being the a wider groove (92), opposed to the notch in the proximal direction, both the groove (92) and the notch (90) being semi-cylindrical (Figure 11) where the wall of the housing (60) is substantially elongate in the proximal and longitudinal direction and defines the semi-cylindrical notch and groove, where a tool could be received in the groove or notch. A proximal portion guide members are mated to the arms (76) via the screw (78), all portions of the guide (60)

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being a portion of the wall of the semi-cylindrical portion. The tabs (flanges 84) are opposed and adapted to seat a splint plate (column 3, lines 59-63) that is capable of being a spine plate, the tabs may be referred to as cut out portions. Both arm carriages (56, 58) contain adjustment mechanisms where either arm can be fixedly or slidably engaged with the support member (54). The adjustment mechanism may contain a leaf spring (column 3, lines 49-51) and is fully lockable. In the case of the spine and specifically in reference to claims 14 and 27, small sections of the spine may be considered flat and lack curvature, specifically the midpoint of the thoracic region or any region that includes only two vertebrae, as it requires more than two points to constitute a curve, furthermore in front to back direction of the human body the spine lacks any curvature whatsoever and additionally it is possible to manipulate the spine in such a way that it may lack curvature, therefore a device that lacks curvature may in fact match the contour of the spine for certain portions, a diagram is provided below in Figure A. In reference to claim 10, the tab portion maintains a substantially concave inner surface that is adapted to match the contour of the implant (column 3, lines 60-63), while the contour may be stepped the profile is still concave as demonstrated by the curved line shown in Figure B below.

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**Conclusion**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Duffner, US Pat# 6796986- adjustable jig; Caspar, US Pat# 5669915-dilling Jig; Wassenaar, US Pat# 1920821- distraction forceps; Serbousek, US Pat# 6066142- drilling guide; Schultheiss, US Pat# 5531751- aiming tube.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert W. Amareld, Jr. whose telephone number is 571-272-6170. The examiner can normally be reached on M-F 9am -5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RWA

**BRIAN E. PELLEGRINO**  
**PRIMARY EXAMINER**

*Brian E Pellegrino*

Robert W Amareld, Jr.  
Examiner  
Art Unit 3738

*Robert W Amareld, Jr.*